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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,258	05/07/2001	Patricia M. Rodier	176/60183 (6-11407-674)	1548

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EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/850,258	RODIER ET AL.
	Examiner	Art Unit
	Jehanne E Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-35,37,38,41 and 42* is/are pending in the application.

4a) Of the above claim(s) *32-35,38 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2/02* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 37 and 41 in the response dated June 19, 2003 is acknowledged. The traversal is on the ground(s) that the claims are closely related and require common areas of search and consideration. This is not found persuasive because a search for methods of screening subjects for autism spectrum (group I) is not required for the search of polypeptides of group II or the antibodies of group III. Likewise, a search of antibodies (group III) is not required for a search of specific polypeptides (group II). Additionally, the consideration of these groups with regard to patentability under 35 USC 101, 112, 102, and 103 are different for each invention. For these reasons and the reasons made of record in the previous office action, the claims are deemed to be drawn to separate and distinct inventions. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 32-35, 37, 38, 41, and 42 are pending in the instant application. Claims 32-35, 38, and 42 are withdrawn from consideration as being drawn to nonelected inventions. An action on the merits of claims 37 and 41 follows.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 37 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As written, the claims are broadly drawn to a polypeptide encoded by a nucleic acid molecule or fragment of at least 15 nucleotides, which contains a single base substitution (claim 37), as well as any polypeptide encoded by a nucleic acid molecule which contains any single base insertion (claim 41). As the claims are written, they are not drawn to any specific substitution or insertion, nor are they limited to polypeptides encoded by any part of SEQ ID NO 1 or SEQ ID NO: 5. For example, the claims are drawn to the polypeptide taught by accession number A30242, which has not been taught or described by the specification.

With regard to claim 37, as written the claim also is more specifically drawn to a polypeptide encoded by a nucleic acid molecule comprising a fragment having at least 15 nucleotides of SEQ ID NO: 1, with a single base substitution at position 218. This recitation broadly encompasses any nucleic acid molecule which need only contain 15 nucleotides from SEQ ID NO: 1 with any nucleic acid sequence on either side. Such a recitation broadly encompasses a large number of nucleic acids including genomic sequences, as well as variant, mutant, and homologs of only a portion of SEQ ID NO: 1, and likewise a large number of polypeptides encoded by such nucleic acids. However, the specification has only taught the single mutant nucleic acid sequence of SEQ ID NO: 3 and the resulting encoded protein of SEQ ID NO: 4, which are not representative of this extremely large genus of possible sequences.

With regard to claim 41, as written the claim also more specifically encompasses a polypeptide encoded by the nucleic acid of SEQ ID NO: 5 with the insertion of any nucleic acid sequence between nucleotides 88 and 89. The number of possible insertions between nucleotides

88 and 89 is extremely large and would result in a large number of different mutant HOXB1 proteins. While the specification has taught the insertion of nine specific nucleotides (ACAGCGCCC) which results in the addition of an extra serine-alanine-histidine trimer in the HoxB1 protein, this is a single variant which is not representative of the large number of possible functionally mutant HoxB1 proteins encompassed by the claims. The specification does not teach or describe whether such mutants would be associated with autism or how the function of the HoxB1 protein would be affected by the extremely large number of possible insertions between nucleotides 88 and 89 of the HoxB1 coding sequence.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 4 and 8, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 37 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by accession number A30242 (December 1989).

The claims are broadly drawn to a polypeptide encoded by a nucleic acid molecule or fragment of at least 15 nucleotides, which contains a single base substitution (claim 37), as well as any polypeptide encoded by a nucleic acid molecule which contains any single base insertion (claim 41). As the claims are written, they are not drawn to any specific substitution or insertion, nor are they limited to polypeptides encoded by any part of SEQ ID NO 1 or SEQ ID NO: 5. Accession number A30242 teaches a polypeptide (inherently encoded by a nucleic acid) which

contains an arginine (one of the possible single base substitution at position 218 of SEQ ID NO: 1 encodes an arginine). With regard to claim 41, as no specific nucleotide sequence is presented, the insertion could be any nucleic acid sequence and thus encode any protein. Therefore, accession number A30242 anticipates claim 41.

Conclusion

7. No claims are allowable over the cited prior art. However, SEQ ID NOS 4 and 8 are free of the cited prior art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Jehanne Souaya
Primary Examiner
Art Unit 1634
9/24/03

Jones, Director
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